

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|--------------------|---|-----------------------|
| MERCK & CO., INC., |) | |
| |) | |
| Plaintiff, |) | |
| |) | C.A. No. 06-230 (GMS) |
| v. |) | |
| |) | |
| APOTEX, INC., |) | |
| |) | |
| Defendant. |) | |

JOINT STATUS REPORT

In light of information provided to plaintiff Merck & Co., Inc. ("Merck") by defendant Apotex, Inc. ("Apotex"), Merck has granted Apotex a covenant not to sue on all of the patents-in-suit in this matter. It is Merck's position that this has eliminated the justiciable controversy between the parties. Apotex's position is it has not. However, because Merck forwarded the covenant to Apotex on July 31, 2006, and the case has not yet been dismissed, pursuant to the Court's July 6, 2006 Re-Notice of Scheduling Conference, and in advance of the Scheduling Conference set for August 8, 2006 at 10:00 a.m., Merck and Apotex submit this Joint Status Report and accompanying jointly-proposed Scheduling Order. (Exhibit 1, Proposed Scheduling Order).

1. Jurisdiction and Service.

The Court has subject matter jurisdiction in this matter, and personal jurisdiction of all parties. Presently, no parties remain to be served.

2. Substance of the Action.

This is a patent infringement action. Merck is the owner through assignment of U.S. Patents Nos. 5,358,941 (the "'941 patent"), 5,681,590 (the "'590 patent"), 5,849,726 (the "'726

patent”), 6,008,207 (the “‘207 patent”), 6,090,410(the “‘410 patent”), 6,194,004 (the “‘004 patent”), 5,994,329 (the “‘329 patent”), 6,015,801 (the “‘801 patent”), and 6,225,294 (the “‘294 patent”) patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex’s ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

Because Apotex seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents before their expiration, Merck alleges that Apotex has infringed the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents pursuant to 35 U.S.C. § 271(e)(2)(A). Merck also alleges that Apotex was aware of the existence of the ‘941, ‘590, ‘726, ‘207, ‘410, ‘004, ‘329, ‘801, and ‘294 patents and was aware that the filing of its ANDA and certification with respect to those patents constituted an act of patent infringement. Merck also alleges that this is an exceptional case under 35 U.S.C. § 285.

Apotex filed a counterclaim for a declaratory judgment that Merck’s patents are invalid and/or not infringed. Apotex also alleged that this is an exceptional case under 35 U.S.C. § 285.

3. Identification of Issues.

The pleadings raise the issues of patent infringement, willful infringement, patent validity, and whether the case is an exceptional one under 35 U.S.C. § 285.

4. Narrowing of Issues.

Merck believes that it is premature to know to what extent, if any, the issues in litigation can be narrowed by agreement or by motions, or whether there are dispositive or partially dispositive issues appropriate for decision on motion. As set forth above, Merck has granted a covenant not to sue to Apotex that eliminates the justiciable controversy between the parties, although it is Apotex's position that it has not.

5. Relief.

Merck seeks (1) a judgment that Apotex has infringed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents, (2) a judgment that this is an exceptional case entitling Merck to its reasonable attorney fees pursuant to 35 U.S.C. § 285, (3) a permanent injunction restraining Apotex from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drug compounds the use of which is claimed in the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents, and (4) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Apotex's ANDA be a date which is not earlier than the later of June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent, or any later expiration of exclusivity to which Merck is or becomes entitled. Merck seeks no damages because, to date,

Apotex has not engaged in the commercial manufacture, use, offer to sell or sale within the United States, or the importation into the United States, of a drug the use of which is claimed in the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents.

In its counterclaim, Apotex seeks: (1) a declaration that the patents are invalid and/or not infringed; and (2) a judgment that this is an exceptional case entitling Apotex to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

6. Amendment of Pleadings.

The accompanying proposed Scheduling Order sets forth the parties' jointly proposed schedule for the amendment of pleadings as October 13, 2006. (Exhibit 1; *see also* Exhibit 2).

7. Joinder of Parties.

The accompanying proposed Scheduling Order sets forth the parties' jointly proposed schedule for the joinder of parties as October 13, 2006. (Exhibit 1; *see also* Exhibit 2).

8. Discovery.

The accompanying proposed Scheduling Order sets forth the parties' jointly proposed schedule for the completion of both fact and expert discovery. (Exhibit 1; *see also* Exhibit 2). At present, Merck believes that discovery will be necessary on the issues of patent infringement, willful infringement, patent validity and exceptional case. Also at present, Merck believes it is premature to know whether discovery can be limited, or whether any less-costly and time-consuming methods are available to obtain necessary information.

9. Estimated Length of Trial.

The accompanying proposed Scheduling Order sets forth the parties' jointly proposed schedule for trial, which sets forth a five (5) day bench trial. (Exhibit 1; *see also* Exhibit 2).

10. Jury Trial.

As this is an ANDA case, Merck's position is that this case should be tried to the bench.

11. Settlement.

As discussed above, Merck has provided a covenant not to sue to Apotex that eliminates the justiciable controversy between the parties, although it is Apotex's position that it has not.

Counsel for the parties have conferred about each of the above matters.

Dated: July 31, 2006

MORRIS, NICHOLS, ARSHT & TUNNELL LLP POTTER ANDERSON & CORROON LLP

/s/ James W. Parrett, Jr.

/s/ Richard L. Horwitz

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Attorneys for Defendants

530824

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19899

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on July 31, 2006 upon the following individuals in the manner indicated:

BY HAND

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19899

BY FACSIMILE

Robert B. Breisblatt, Esquire
WELSH & KATZ, LTD.
120 South Riverside Plaza; 22nd Floor
Chicago, IL 60606

/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|--------------------|---|-----------------------|
| MERCK & CO., INC., |) | |
| |) | |
| Plaintiff, |) | |
| |) | C.A. No. 06-230 (GMS) |
| v. |) | |
| |) | |
| APOTEX, INC., |) | |
| |) | |
| Defendant. |) | |

RULE 16 SCHEDULING ORDER

This ____ day of _____ 200__, the Court having conducted a Rule 16 Scheduling Conference pursuant to Local Rule 16.2(b) on _____, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation or binding arbitration;

IT IS ORDERED that:

1. **Rule 26(a) Initial Disclosures.** Unless otherwise agreed to by the parties, they shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a) on or before August 21, 2006.¹
2. **Joinder of Other Parties and Amendment of Pleadings.** All motions to join other parties and amend the pleadings shall be filed on or before October 13, 2006.

¹ In light of information provided to Merck by Apotex, Merck has granted Apotex a covenant not to sue on all of the patents-in-suit in this matter. It is Merck's position that this has eliminated the justiciable controversy between the parties. Apotex's position is it has not. However, because Merck forwarded the covenant to Apotex on July 31, 2006, and the case has not yet been dismissed, the parties submit this Rule 16 Scheduling Order in compliance with the Court's July 6, 2006 Order.

3. **Reliance Upon Advice of Counsel.** Defendant shall inform plaintiff whether it intends to rely upon advice of counsel as a defense to willful infringement no later than September 20, 2006. If defendant elects to rely on advice of counsel as a defense to willful infringement, defendant shall produce any such opinions on which defendant intends to rely to plaintiff no later than October 20, 2006.

4. **Markman Claim Construction Hearing.** The parties currently believe there is no need for a *Markman* hearing. However, as the parties contentions regarding infringement and/or invalidity become known during discovery, the parties may request that a *Markman* hearing be scheduled.

5. **Discovery.** All fact discovery in this case shall be initiated so that it will be completed on or before February 20, 2007. Expert Discovery in this case shall be initiated so that it will be completed on or before April 5, 2007.

a. **Discovery and Scheduling Matters:** Should counsel find they are unable to resolve a discovery or scheduling matter, the party seeking the relief shall contact chambers at (302) 573-6470 to schedule a telephone conference. Not less than forty-eight hours prior to the teleconference, the parties shall file with the court, via electronic means (CM/ECF), a **joint, non-argumentative** letter agenda not to exceed two (2) pages outlining the issue(s) in dispute. A sample letter can be located on this Court's website at www.ded.uscourts.gov. Should the Court find further briefing necessary upon conclusion of the telephone conference, unless otherwise directed, the party seeking relief shall file with the Court a **TWO PAGE LETTER**, exclusive of exhibits, describing the issues in contention. The responding party shall file within five (5) days from the date of service of the opening letter an answering letter of no

more than **TWO PAGES**. The party seeking relief may then file a reply letter of no more than **TWO PAGES** within three (3) days from the date of service of the answering letter.

b. Maximum of twenty-five (25) interrogatories, including contention interrogatories, for each side.

c. Maximum of fifty (50) requests for admission by each side.

d. Maximum of ten (10) depositions by plaintiff and ten (10) by defendant, excluding expert depositions.

e. Reports from retained experts required by Fed. R. Civ. P. 26(a)(2) are due from the party having the burden of proof by February 5, 2007; rebuttal expert reports are due by March 5, 2007.

6. **Confidential Information and Papers Filed Under Seal.** Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, they should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date of this order. When filing papers under seal, counsel should deliver to the Clerk an original and two copies of the papers.

If after making a diligent effort the parties are unable to agree on the contents of the joint proposed protective order, then they shall follow the dispute resolution process outlined in paragraph 5(a).

7. **Settlement Conference.** Pursuant to 28 U.S.C. § 636, this matter is referred to the United States Magistrate for the purpose of exploring the possibility of a settlement. If the parties agree that the possibility of settlement may be enhanced by such

referral, the parties shall contact United States Magistrate Judge Thyng to schedule a settlement conference with counsel and the clients.

8. **Summary Judgment Motions.** Prior to filing any summary judgment motion, the parties must submit letter briefs seeking permission to file the motion. The opening letter brief shall be no longer than five (5) pages and shall be filed with the Court no later than May 9, 2007. Answering letter briefs shall be no longer than five (5) pages and filed with the Court no later than May 23, 2007. Reply letter briefs shall be no longer than three (3) pages and filed with the Court on or before May 30, 2007. The Court shall hold a Status Conference to hear argument and to determine whether the filing of any motion will be permitted on June 6, 2007 at 9:30 a.m. **Unless the Court directs otherwise, no letter requests to file a motion for summary judgment may be filed at a time before the dates set forth in paragraph 8.**

9. **Case Dispositive Motions.** All case dispositive motions and an opening brief and affidavits, if any, in support of the motion shall be served and filed on or before June 15, 2007. Briefing will be presented pursuant to the Court's Local Rules, unless the parties agree to an alternative briefing schedule. Any such agreement shall be in writing and filed with the Court for the Court's approval. Any request for extensions of time as set forth in this Scheduling Order **must** be accompanied by an explanation or your request will be denied.

10. **Applications by Motion.** Except as provided in this Scheduling Order or for matters relating to scheduling, any application to the Court shall be by written motion filed, via electronic means (CM/ECF). Unless otherwise requested by the Court, counsel shall **not** deliver copies of papers or correspondence to Chambers. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

11. **Oral Argument.** If the Court believes that oral argument is necessary, the Court will schedule a hearing Pursuant to District of Delaware Local Rule 7.1.4.

12. **Status/Daubert Conference.** On or before April 16, 2007 (one week prior to Daubert teleconference), the parties shall submit a joint agenda identifying any Daubert issues that the parties intend to raise. The Court will hold a telephone conference on April 23, 2007 at 9:30 a.m. to discuss Daubert issues identified in the joint agenda.

13. **Pretrial Conference.** On September 24, 2007, beginning at 10:00 a.m., the Court will hold a Pretrial Conference in Chambers with counsel. Unless otherwise ordered by the Court, the parties should assume that filing the Joint Pretrial Order (a sample form of Pretrial Order can be located on this Court's website at www.ded.uscourts.gov) satisfies the pretrial disclosure requirement in Federal Rule of Civil Procedure 26(a)(3). Thirty (30) days before the Joint Proposed Pretrial Order is due, plaintiff's counsel shall forward to defendant's counsel a draft of the pretrial order containing the information plaintiff proposes to include in the draft. Defendant's counsel shall, in turn, provide to plaintiff's counsel any comments on the plaintiff's draft as well as the information defendant proposes to include in the proposed pretrial order. Motions *in limine*: No party shall file more than ten (10) motions *in limine*. Briefs (**opening, answering and reply**) on all motions *in limine* shall be filed on the following schedule: Opening briefs due on August 3, 2007; answering briefs due on August 17, 2007; reply briefs due on August 24, 2007. Opening and answering briefs shall not exceed five (5) pages and reply briefs shall not exceed three (3) pages. The parties shall file with the Court the joint proposed final pretrial order with the information required by the form of Final Pretrial Order which accompanies this Scheduling Order on or before August 27, 2007.

14. **Trial.** This matter is scheduled for a 5 day bench trial beginning at 9:00 a.m. on October 22, 2007.

15. **Scheduling.** The parties shall contact Chambers at (302) 573-6470, only in situations where scheduling relief is sought, and only then when ALL participating counsel is on the line for purposes of selecting a new date.

UNITED STATES DISTRICT JUDGE

530806

EXHIBIT 2

Proposed Case Schedule**Merck & Co., Inc., v. Apotex, Inc. C.A. No. 06-230 (GMS)**

| Description | Proposed Date |
|---|---|
| Rule 26 (a) Initial Disclosures | August 21, 2006 |
| Joinder of Parties and Amendment of Pleadings | October 13, 2006 |
| Reliance Upon Advice of Counsel | September 20, 2006; Produce Opinions: October 20, 2006 |
| <i>Markman</i> Claim Construction Hearing | (parties agree no need for hearing) |
| Fact Discovery | February 20, 2006 |
| Expert Discovery | April 5, 2007 |
| Expert Reports | Opening: February 5, 2007 Rebuttal: March 5, 2007 |
| Letter Briefs requesting permission to file Summary Judgment Motions | Opening: May 9, 2007 Answering: May 23, 2007 Reply: May 30, 2007 |
| Status Conference | June 6, 2007 at 9:30 a.m. |
| Case Dispositive Motions | June 15, 2007 |
| Joint Agenda re: Daubert Issues | April 16, 2007 |
| Status/Daubert Conference | April 23, 2007 at 9:30 a.m. |
| Motions in Limine | Opening: August 3, 2007 Answering: August 17, 2007 Reply: August 24, 2007 |
| Pretrial Order | August 27, 2007 |
| Pretrial Conference | September 24, 2007 at 10:00 a.m. |
| Trial- 5 Day Bench Trial | October 22, 2007 at 9:00 a.m. |